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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,006	04/12/2004	Akira Yamamoto	P24816	1571

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GREENBLUM & BERNSTEIN, P.L.C.  
1950 ROLAND CLARKE PLACE  
RESTON, VA 20191

EXAMINER
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SINGH, SATYENDRA K

ART UNIT	PAPER NUMBER
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1657

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	01/08/2007	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 01/08/2007.

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gbpatent@gbpatent.com  
pto@gbpatent.com

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/822,006	YAMAMOTO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Satyendra K. Singh	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 31-38 is/are pending in the application.
- 4a) Of the above claim(s) 1-30 and 39-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/4/04; 9/28/04; 9/29/05</u>                                  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant's response filed with the office on October 27<sup>th</sup> 2006 is duly acknowledged.

Claims 1-30 and 39-47 (inventions of group I and III) have been withdrawn from further consideration.

Claims 31-38 (elected invention of group II; cell culture carriers) have been examined in this office action.

#### ***Election/Restrictions***

Applicant's **election with traverse** of group II (claims 31-38, directed to "cell culture carriers") in the reply filed on October 27<sup>th</sup> 2006 is acknowledged. The traversal is on the ground(s) that "there would not appear to be a serious burden on the Patent and Trademark Office in examining claims directed to the non-elected inventions since the examination would overlap....found in the same search class 435" (see applicant's remarks, page 3, last paragraph, and page 4, 1<sup>st</sup> paragraph, in particular). This is not found persuasive because burden on the office lies not only in the search of US Patents, but in the search for literature and foreign patents and examination of the claim language and specification for compliance with the statutes concerning new matter, distinctness, scope of enablement, and double patenting issues. Although, the inventions of groups I, II and III are classified under same class 435, their further classification will depend on the various method steps involved and the components used, that are not necessarily co-extensive in scope, as presented in the instant invention as claimed. For example, a search for magnetic field generator (see instant claim

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39) would not necessarily be co-extensive with the search for the product components and various method steps used for culturing cells on a carrier, as claimed. Moreover, as pointed out in the restriction requirement as set forth by the previous office action (mailed on September 27<sup>th</sup> 2006; see page 5, 2<sup>nd</sup> and 3<sup>rd</sup> paragraphs, in particular), if the product claims of group II are found to be allowable, the process of use claims (properly depending from the allowable product claim) will be rejoined and further examined on their merits for their allowability as per the provisions set forth in MPEP § 821.04.

The requirement is still deemed proper and is therefore made FINAL.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 31 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being **indefinite** for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims recite the limitation “**allowed** to adhere” to the cell culture carrier, which is confusing. It is not clear as to what exactly the term “**allowed**” signifies in relation to the structural features for the product (i.e. cell culture carriers) being claimed. Similarly, it is unclear, and the instant disclosure does not provide the details as to what degree or type of allowance (spatial, temporal, or any other) is required by the claimed limitation (and if there is any specific type of cell that is allowed to adhere to the

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carrier) in order to fulfill the requirement for arriving at the ration of A/B, as defined in the instant claim 33. Appropriate explanation/correction is required.

2. Claim 35 is rejected under 35 U.S.C. 112, second paragraph, as being **indefinite** for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 35 recites "wherein the coating layer is **mainly** made of calcium phosphate-based compound", which is ambiguous. It is not clear as to what proportion or amount of the calcium phosphate-based compound is required by the limitation as claimed, and as to what proportion of any other constituents or components are permitted by such claimed limitation. The meets and bounds of the invention as claimed are not defined in the claim as well as the instant disclosure provided by the applicants, and thus, the use of term "mainly" renders the claimed invention indefinite. Appropriate explanation/correction is required. For examination purposes herein, the term "mainly" has been construed to its general meaning of the word ("principally" or "**chiefly**" or "mostly" or **for the most part**, as indicated in Merriam-Webster online dictionary; [U]) that means a coating layer being made of **more than 50%** of a calcium phosphate-based (CaP) compound, as claimed.

3. Claims 36 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being **indefinite** for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims recite the term "**fine** particles", which is confusing. It is not clear as to what degree of "finess" is required and/or encompassed by the claimed limitation, or how to determine/ascertain the degree of "finess" of the particles of CaP-based

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compound that is to be used to coat the cell culture carriers of the instant invention. Since, the instant disclosure fails to provide an explicit definition of the term "fine" in the context of the particles of CaP-based compound used in the invention (and since, one of ordinary skill in the art would not be able to clearly envision the "fineness" of the CaP particles required; see the prior art [U] for the definition), the use of such a term renders the invention as claimed, indefinite. Appropriate explanation/correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**1. Claims 31, 33 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Nilsson et al (GB 2,093,040A, published as WO 82/00660; IDS).**

Claims are generally directed to **cell culture carriers** comprising a **magnetic particle** having a surface, and a **coating layer**, which is provided to cover at least a part of the surface of the magnetic particle; wherein the ratio of **A/B** (average particle size over length of the cell; as defined in instant claim 33) is 2 to 100; and wherein the **particle size** of the cell culture carriers is in the range of 50 to 500  $\mu\text{m}$  (instant claim 34).

Nilsson et al (IDS) teach cell culture carriers (microcarriers, for use in the immobilization and cultivation of anchorage-dependent animal cells in and on the surface of the carriers; see Nilsson et al, WIPO document, abstract, page 1, 1<sup>st</sup>

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paragraph, in particular) comprising a magnetic particle (consisting essentially of  $\text{Fe}_3\text{O}_4$ ) having a surface, and a coating layer of gelatin or chitosan polymers (that can be cross-linked for improving mechanical strength of the microcarrier beads), and wherein the carriers have a particle size in the range of 100 to 250  $\mu\text{m}$  (see Nilsson et al, pages 10-11, and claims, in particular). The limitation of claim 33 is also met by the prior art, Nilsson et al because the ratio A/B (as defined in the instant claim 33; and taking the length of an average eukaryotic animal cell used for *in vitro* culture, to be in the range of 10-30  $\mu\text{m}$ ) taught by the prior art (i.e. microbeads/microcarriers of average particle size 100- 250  $\mu\text{m}$ ; results in an approximate ratio of A/B to be in the range of 5-50) meets the limitation of the invention as claimed.

**2. Claims 31, 32-34, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Henderson (US Patent 4,448,884; IDS).**

Claims are generally directed to **cell culture carriers** comprising a **magnetic particle** having a surface, and a **coating layer**, which is provided to cover at least a part of the surface of the magnetic particle; wherein a density of the carrier is in the range of 0.8 to 2.5  $\text{g/cm}^3$  (claim 32); wherein the ratio of **A/B** (average particle size over length of the cell; as defined in instant claim 33) is 2 to 100; wherein the **particle size** of the cell culture carriers is in the range of 50 to 500  $\mu\text{m}$  (instant claim 34); and wherein the magnetic particles are formed by compounding a **resin material** and a **magnetic material** (claim 38).

Henderson (IDS) teaches a glass-surface microcarrier for growth of cell cultures (i.e. substantially buoyant carriers for use in anchorage-dependent cell cultivation; see Henderson, abstract, object and summary of the invention, and claims, in particular) comprising microspheres of polymeric material (such as resin material such as polystyrene or polyethylene having a precursor bulk density of about 1g/cc; see Henderson, column2, lines 62-65, in particular) with a

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particle size of 50 to 500 microns (preferably 106 to 200 microns; see Henderson, column 2, lines 45-53, in particular) that can be coated (thickness between 300 Angstrom to 1 mm; see column 3, 2<sup>nd</sup> paragraph, in particular) with a magnetic material, or the magnetic material may be included by occlusion within the polymeric beads or spheres ( or a paramagnetic material; see Henderson, column 4, 1<sup>st</sup> paragraph, in particular) to yield a magnetic particle or a magnetic microcarrier that can be further coated with "silicate glass" material (in order to reduce toxicity and impart mechanical strength to the microcarriers) in such a way to have a little measurable effect upon overall density of the resulting microcarriers (see Henderson, column 3, 2<sup>nd</sup> paragraph, line 11-17, in particular).

The limitation of claim 33 is also met by the prior art (Henderson), because the ratio A/B (as defined in the instant claim 33; and assuming the length of an average eukaryotic animal cell normally used for *in vitro* culture, to be in the range of 10-30  $\mu\text{m}$ ) taught by the prior art (i.e. microcarriers of average particle size 50 to 500  $\mu\text{m}$ ; results in an approximate ratio of A/B to be in the range of 2 to 25) meets the limitation of the invention as claimed.

**3. Claims 31, 32-34, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Mathew (IDS).**

Claims are generally directed to **cell culture carriers** comprising a **magnetic particle** having a surface, and a **coating layer**, which is provided to cover at least a part of the surface of the magnetic particle; wherein a density of the carrier is in the range of 0.8 to 2.5 g/cm<sup>3</sup> (claim 32); wherein the ratio of **A/B** (average particle size over length of the cell; as defined in instant claim 33) is 2 to 100; wherein the **particle size** of the cell culture carriers is in the range of 50 to 500  $\mu\text{m}$  (instant claim 34); and wherein the magnetic particles are formed by compounding a **resin material** and a **magnetic material** (claim 38).



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Mathew (IDS) teaches cell culture microcarriers comprising a magnetic particle having a surface (comprising polymeric resin beads made of polystyrene; see Mathew, pages 56-77, page 60 and 65, in particular), and a coating layer (comprising collagen; see Mathew, page figure 5.1, and table 5.2, in particular), which is provided to cover at least a part of the surface of the magnetic particle; wherein a density of the carrier is in the range of 0.8 to 2.5 g/cm<sup>3</sup> (see Mathew, table 5.1, in particular); wherein the particle size of the cell culture carriers is in the range of 100 to 425  $\mu$ m (see Mathew, page 77, 2<sup>nd</sup> paragraph, in particular); and wherein the magnetic particles are formed by compounding a resin material and a magnetic material (see Mathew, page 61, figure 5.1, in particular); and wherein the ratio of A/B (average particle size over length of the cell; as defined in instant claim 33) is within the range of 2 to 20 (assuming the length of an average eukaryotic animal cell normally used for *in vitro* culture, to be in the range of 10-30  $\mu$ m).

*"[E]ven though **product-by-process** claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).*

*As per MPEP 2111.01, during examination, the claims must be interpreted as broadly as their terms reasonably allow. In re American Academy of Science Tech Center, F.3d, 2004 WL 1067528 (Fed. Cir. May 13, 2004)(The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their **broadest reasonable interpretation**). This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).*

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 31-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Starling et al (US Patent 6,210,715 B1; [A]) or Kitano et al (US Patent 5,540,995; [B]) in view of Nilsson et al (GB 2,093,040A, published as WO 82/00660; IDS).

Claims are generally directed to **cell culture carriers** (viz: useful for anchorage-dependent cell cultivation) comprising a **magnetic particle** having a surface, and a **coating layer**, which is provided to cover at least a part of the surface of the magnetic particle; wherein a density of the carrier is in the range of 0.8 to 2.5 g/cm<sup>3</sup> (claim 32); wherein the **ratio of A/B** (average particle size over length of the cell being adhered and cultured; as defined in instant claim 33) is 2 to 100; wherein the **particle size** of the cell culture carriers is in the range of 50 to 500  $\mu$ m (instant claim 34); wherein the coating layer is mainly made of a **calcium-phosphate**-based compound (claim 35); wherein said coating layer is formed from fine, porous particles being **partially embedded** into the magnetic particle at the vicinity of the surface thereof, and is **formed by colliding** said porous particles to the surface of said magnetic particle (see instant claims 36 and 37); and wherein the magnetic particles are formed by **compounding a resin material** and a **magnetic material** (claim 38).

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Starling et al [A] teach cell culture carriers to which cells are allowed to adhere to and grow on surfaces thereof, wherein each of the carriers comprise glass or polymeric (such as polystyrene, polyethylene, dextran, gelatin, and/or glass) beads (suspendable or non-suspendable microspheres; solid or hollow; see Starling et al, abstract, summary of the invention, figures 1-1 and 1-2, column 10, 1<sup>st</sup> paragraph, in particular) that can be coated with a layer of calcium phosphate-based compound (CaP, such as hydroxyapatite, ticalcium phosphate, or other CaPs; see Starling et al, column 4, lines 1-3, in particular) to cover at least a part of the surface of the microspheres so that the cells are allowed to adhere thereto (also see Starling et al, examples 1-7, example 3 in particular); wherein the cell culture carriers have an average particle size in the range of 100 microns to 6000 microns (thus also meeting the limitations of claim 33); wherein the density of the carriers is in the range of 1.2 to 2 g/cc (which can be varied depending on the components of the microbeads and various desired applications; see Starling et al, column 3, lines 47-50, and examples 1-13, in general); wherein the coating layer is formed from porous particles of calcium phosphate-based compound using suitable processes such as spray granulation or disk pelletization (that are well known in the art; see Starling et al, column 16, last paragraph, in particular), and are sintered such that the porous fine particles of CaP-based compound are partially embedded onto the surface of the polymeric microbeads (see Starling et al, examples 3-4, in particular), and provide increased surface area for greater activity in cell culturing applications (see Starling et al, column 17, lines 2-8, in particular).

Kitano et al [B] teach granular polymer composites (average particle size within the range of 1.2 to 30 microns; see abstract, summary of the invention, examples 1-7, and claims, in particular) comprising polymer beads (thermoplastic resins such as nylon, polystyrene, PMMA or polyethylene; see column 3, 2<sup>nd</sup> paragraph, in particular) having coated on the surface thereof a calcium phosphate-based compound (such as hydroxyapatite; see Kitano et al, column 3, last paragraph, in particular) such that the microcarriers or microbeads are suitable for allowing cells to adhere onto their surface (and thus suitable for the cell culture and/or related medical and diagnostic applications); wherein the coating layer is formed of fine porous CaP particles that are partially embedded/penetrated into the polymeric microbeads at the vicinity of the surface thereof (see Kitano et al, column 2, lines 10-16, in particular) using a process that requires colliding porous CaP particles to the surface of the polymeric microbeads or microspheres (using Nara Hybridization system; see Kitano et al, column 5, 2<sup>nd</sup> paragraph, and examples 1-7, in particular); and wherein the density of the composite microcarriers range within 0.9 to 1.2 g/cc (see Kitano et al, column 3, lines 39-47, in particular).

However, a cell culture carrier comprising a **magnetic particle** in combination with a polymeric resin material, having a surface that can be coated with CaP-based compound (as recited in the instant claims 31 and 38), is not explicitly disclosed by the teachings of Starling et al, or Kitano et al.

Nilsson et al (IDS) teach cell culture carriers (microcarriers, suitable for use in the immobilization and cultivation of anchorage-dependent animal cells in

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and on the surface of the carriers; see Nilsson et al, WIPO document, abstract, page 1, 1<sup>st</sup> paragraph, in particular) comprising a magnetic particle (consisting essentially of  $\text{Fe}_3\text{O}_4$ ) having a surface, and a coating layer of gelatin or chitosan polymers (that can be cross-linked for improving mechanical strength of the microcarrier beads), and wherein the carriers have a particle size in the range of 100 to 250  $\mu\text{m}$  (see Nilsson et al, pages 10-11, and claims, in particular). The limitation of claim 33 is also met by the prior art, Nilsson et al because the ratio A/B (as defined in the instant claim 33; and taking the length of an average eukaryotic animal cell used for *in vitro* culture, to be in the range of 10-30  $\mu\text{m}$ ) taught by the prior art (i.e. beads/microcarriers of average particle size 100- 250  $\mu\text{m}$ ; results in an approximate ratio of A/B to be in the range of 5-50) meets the limitation of the invention as claimed.

It would have been obvious to a person of ordinary skill in the art at the time this invention was made to incorporate magnetic particles (as taught by Nilsson et al) into the polymeric microbeads or cell culture composition of Starling et al or Kitano et al such that the cell culture carriers have a magnetic particle having a surface, and a coating layer formed of porous, particulate CaP-based compound so that the cells are allowed to adhere to the surface thereof.

A person of ordinary skill in the art would have been motivated to modify the composition of Starling et al or Kitano et al by incorporating the magnetic particles in the microbeads, because Nilsson et al discloses the benefits of incorporating magnetic particles in the microcarriers in order to permit the use of

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an external magnetic field to stir, suspend and/or isolate the microcarriers (see Nilsson et al, abstract, in particular).

One of ordinary skill in the art would have had a reasonable expectation of success in modifying the cell culture microcarriers of Starling et al or Kitano et al using the teachings of Nilsson et al as they explicitly disclose the process of making such microcarriers (that are suitable for cell culture applications) by incorporating Fe<sub>3</sub>O<sub>4</sub> particles in cross-linked gelatin beads (see Nilsson et al, pages 10-11, in particular).

Thus, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill in the art at the time the claimed invention was made.

As per MPEP 2144.06, "It is *prima facie* obvious to **combine two compositions** each of which is taught by the prior art to be **useful for the same purpose**, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

"[E]ven though **product-by-process** claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

As per MPEP 2111.01, during examination, the claims must be interpreted as broadly as their terms reasonably allow. *In re American Academy of Science Tech Center*, F.3d, 2004 WL 1067528 (Fed. Cir. May 13, 2004) (The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their **broadest reasonable interpretation**). This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

### **Obviousness-type Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application

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claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 31-38 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 11/190,868 (common inventor and same assignee, PENTEX Corporation, Tokyo, Japan). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims in the co-pending application are also directed to a **cell culture carrier** having a surface to which cells are allowed to adhere and grow, which is mainly made of a **resin** material that can comprise a **magnetic** material, and the surface of said carrier can be coated with a **calcium phosphate**-based compound, wherein the **particle size** and the **density** of each of the cell culture carriers is in the range of 10 to 2000  $\mu\text{m}$  and 1.01 to 1.5 g/cc, respectively (see specific recitations of claims 1-5, 8, and 10 of the copending application 11/190,868). The two sets of claims are clearly co-extensive, and therefore, an obviousness-type double patenting rejection is proper.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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**Conclusion**

**NO claims are allowed.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyendra K. Singh whose telephone number is 571-272-8790. The examiner can normally be reached on 9-5MF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Satyendra K. Singh  
Patent Examiner  
Art Unit 1657

  
SANDRA E. SAUCIER  
PRIMARY EXAMINER